Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Summary of Meeting: December 13, 2012

CAG members present in person:

Loren Hiratzka
David Williams
Lisa Myers
Yuri Deychak
Gregory Dehmer
Charles Chambers
Christopher Haas
Keith Horvath
Paul Massimiano
Deborah Harper
Peter Horneffer
James Gammie
David Zimrin
Jeffrey Quartner
Mitchell Schwartz
Sharon Sanders
Richard Pomerantz

CAG members participating by phone: John Shuck, Thomas Aversano, Lori Hollowell

Staff:

Ben Steffen
Paul Parker
Christina Daw
Suellen Wideman

Presiding Co-Chairs **David Williams, MD**, and **Loren Hiratzka, MD,** opened the meeting and asked for introductions.

Dr. Williams outlined the CAG's ultimate goals – the group and MHCC staff will eventually work up a summary and, if there is not consensus, a minority report. The remaining topics for the PCI discussion will be patient selection and how PCI should be performed. The Commission is not looking for details but broad principles that relate to patient welfare. Today's meeting will focus on Cardiac Surgery; however, there are topics to finish with respect to PCI, e.g., patient selection and how PCI should be performed. The CAG has not yet discussed PCI monitoring and how to respond to programs that don't meet guidelines; this discussion can be done together for PCI and Cardiac Surgery.

While no meeting has been planned for February, both co-chairs suggested the benefit of having more frequent meetings. Dr. Williams suggested a February meeting, and also that future meetings be longer, from 12:30-4:00, since some people are coming from a distance, and the travel takes up a day anyway.

Paul Parker expressed regret to the members representing hospitals, that the topic of this meeting had changed from PCI to Cardiac Surgery on short notice. The group discussed a possible February meeting, to devote to peer review and associated topics. Members will be polled about availability for a February meeting. At the March 14 meeting (the final scheduled meeting), the CAG would pivot back to data systems and monitoring. Paul anticipates that, for the March meeting, staff will prepare materials for discussion on the process for Certificate of Conformance and Certificate of Ongoing Performance. A date for a possible meeting in April was also suggested by Ben Steffen in case the work of the CAG is not completed in March. MHCC staff expects that, after the final CAG meeting, a draft report will be sent out to the group for review and comment, and an opportunity for members to file dissenting opinions or minority reports would be appropriate at that time. Staff will use the CAG's advice and recommendations to develop the regulatory process mandated in HB 1141.

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Christina Daw referred the group to handouts including maps showing the distribution of Maryland hospitals providing PCI and cardiac surgery services. The map from MIEMSS shows Cardiac Interventional Centers with the geographic areas around these hospitals within specified drive times. She also thanked CAG members who had provided comments on the previous meeting's PCI discussion document.

Presentation by Keith Horvath, MD: Society of Thoracic Surgeons' National Cardiac Database

Keith Horvath, who performs cardiac surgery in Maryland and is the STS representative to the CAG described the STS National Cardiac Database (NCD), using a slide presentation. The STS NCD is 23 years old. It started as a log system, but it has become a "premier" medical database for the government and organizations to monitor and improve quality care. (Slides can be found at www.mhcc.dhmh.maryland.gov/Health Community/Clinical Advisory Group on Cardiac Surgery and PCI Services/The Society of Thoracic Surgeons National Cardiac Database - Keith Horvath, MD)

Summary of Questions ("Q") and Discussion ("D"):

Q: Do all of the hospitals participate?

Keith Horvath: Currently 95% of all centers participate in STS NCD; urbanized areas and Certificate of Need states have high participation. Among the 5% of hospitals not participating, many are in rural locations, and are small hospitals that find that the STS NCD participation costs are too steep. All 10 of the cardiac surgery hospitals in Maryland participate in the STS database.

D: Data entry procedures vary by site; e.g., at Dr. Horvath's hospital, data are entered at various stages by surgeons and nurse practitioners, while administrative staff enter demographic information. Detailed data reports are generated and sent to institutions quarterly, with risk-adjusted benchmarking for regional peer and national comparisons sent every 6 months. Some changes in medical practice have been made following STS' established practice of collecting data; e.g., increased use of the internal mammary artery (IMA) as grafts for CABG after such information on use of the IMA was systematically collected and reviewed. Duke Clinical Research Institute (DCRI) harvests the data for STS for analysis and reports.

STS has also developed a quality measurement program, incorporating measures from the National Quality Forum's National Voluntary Consensus Standards for Cardiac Surgery, as well as recommendations from the Institute of Medicine 2006 report and elements from the STS NCD. STS uses 11 NQF measures from four Quality of Care Domains: perioperative care; intraoperative care, risk-adjusted mortality; and risk-adjusted morbidity. A measure of procedure volume is not included because of concern that volume is a poor surrogate for quality; however, use of minimum thresholds may have value. STS developed a composite score (published in *Annals of Thoracic Surgery*, 2007) and created a "star rating" system derived from the composite score; star ratings are given two times a year. *Consumer Reports Health* publishes the hospital star ratings annually. The report process includes initial data cleaning by STS, follow-up response by hospitals, and final versions of the data report. The reports are released usually approximately six months after data comes in. The composite score is calculated using risk-adjusted mortality, risk-adjusted any-or-none morbidity, use of the internal mammary artery, and use of all evidence-based perioperative medications.

Q: When looking at mortality ("avoidance of mortality") within the relatively small range shown in the data, can a hospital get One Star with 92% survival, then Two Stars for 94% survival?

Dr. Horvath: Avoidance of mortality has a tight range but the measure can tell if a hospital is significantly above or below the national average.

Q: Is there a difference clinically?

Dr. Horvath: The system is trying to show whether patient care is significantly above or below average, based on the composite measure. It may be a small range for survival, but with the number of patients, it is a huge data set.
Q: What is the distribution of star ratings?

74% of programs are Two Star; 13-14% are Three Star and 10-12% are One Star; the percent of One Star programs has decreased over time

D: STS Auditing: The STS data are audited at five percent of participating sites per year by completely independent auditors. The auditing consists of comparing data to the source documents in the patient record. After the first few years of the STS auditing program, reports for CABG showed 96% agreement between data expert subcommittee and audit. Next year, eight percent of sites will be audited.

Other STS Activities: STS has established in-house research. E.g., in a paper from the ASCERT study, a prediction model for CABG was developed. The STS database encompasses the vast majority of CS cases performed in the United States. The database is risk-adjusted, validated, and audited; it also provides composite scoring and may be able in the future to be used as a tool for comparative effectiveness research. Audit results are fed back to the sites for quality improvement purposes.

Q: Is there an obligation to report significant outcomes?

Dr. Horvath: STS only feeds back reports to the site.

Q: How does the STS composite score compare to MACE score?

Dr. Horvath: The STS composite score involves not only outcomes, but incorporates processes of care and other evidence-based data components, for example use of internal mammary artery.

Q: Regarding the star rating system, does everyone get a star rating?

Dr. Horvath: Everyone always gets a rating from 1 to3.

Q: How does this approach compare to England and other countries?

Dr. Horvath: No other systems have done this risk-adjustment with composite scoring. Dr. Hiratzka noted that it is particularly unique in the range of data evaluated, including pre-, inter-, and post-op data. Follow up measurement is done for in-hospital and 30 days post-discharge.

Q: How are the documents reviewed?

Dr. Hiratzka: They use source documents, such as operative reports.

Q: (Dr. Williams) Is the data available to agencies like MHCC?

Dr. Horvath: You would have to request the data from the hospitals. In some states, they have to send the data to a state agency. [Note: In Maryland, there is not currently a state requirement that cardiac surgery hospitals submit STS data for review.]

Presentation by Loren Hiratzka, MD: CABG Volumes and Outcomes

Dr. Hiratzka used slides (slides found at mhcc.dhmh.maryland.gov/Health Community/Clinical Advisory Group on Cardiac Surgery and PCI Services/CABG Volume and Outcomes - Loren Hiratzka, MD) in this presentation. There is a volume - outcome relationship of some kind, as demonstrated by a series of studies, with large samples and varying populations. Overall, there is a significant difference in mortality -- as volume increased, mortality decreased. However, some studies showed heterogeneity in outcomes at low and high volume (E.g., some low volume programs had good/excellent outcomes, while other low volume programs had poor outcomes). In composite scores by volume, lower volume programs have worse composite scores, and scores tend to drop as the volume gets lower.

In research of Japanese cardiac surgery programs, findings showed an increase in risk-adjusted mortality in low volume programs (over three years); for patients under 65, slight difference in risk-adjusted mortality; over 65, difference is much greater (increased mortality). In Japan, however, most programs have a case volume of less than 100 cases per year.

The key question for the CAG to address: **Is there a population benefit to limiting low volume cardiac surgery programs?**

Summary of Questions ("Q") and Discussion ("D"):

Q: High volume programs probably have a cardio-thoracic residency program, so someone is always available to crack open a chest. Does this make a difference?

Dr. Hiratzka: It seems to be mostly process driven [rather than presence of residency program, per se]. Rich Prager, a cardiac surgeon in Michigan, has noted that in Michigan, there are many good programs with volume of 100-200, because they pick patients well and have good processes. The AHA/AHA CABG guideline committee has struggled with the volume issue. Based on data from states and Ontario, if you put a target volume at 125, most of the problem of elevated mortality disappears.

Q: Where are volumes in Maryland?

Dr. Gammie: The median is 299 cases; the range is approximately 30 to 800)

Q: (Dr. Aversano) One of the arguments for volume considerations is, if you have low volumes, it affects quality. However, it is difficult to assess quality at lower-volume programs because of the volatility of data. It takes multiple years to adequately assess mortality for low-volume programs. How many years do you want to wait if it looks bad?

Dr. Hiratzka: By the next period(s), using successive blocks of data. You want to see if a program consistently has only a One Star rating.

Presentation by Loren Hiratzka, MD: Oversight of Cardiac Surgery

Dr. Hiratzka presented his draft ("straw man") proposal for oversight of cardiac surgery in Maryland, for consideration by the CAG. (Slides can be found at www. mhcc.dhmh.maryland.gov/Health Community/Clinical Advisory Group on Cardiac Surgery and PCI Services/Recommendations on Cardiac Surgery and the Development of a Cardiac Surgery Subcommittee - Loren Hiratzka, MD)

Following is a summary:

1. Purpose of the Program
   - ♥ Oversee cardiac surgery program deployment and quality of cardiac surgical care for all Maryland patients and hospitals.
   - ♥ Provide opportunities for collaborative quality improvement initiatives for all participants.

2. Maryland would have a standing Clinical Advisory Committee (CAG) Cardiac Surgery Subcommittee (CSS).
   - ♥ Two representatives of each hospital providing cardiac surgery services: one surgeon, one hospital representative
   - ♥ Other clinical and administrative members of the CAG to be determined
   - ♥ MHCC to provide regulatory perspective, support staff and resources for all CAG activities

3. Functional elements of the CAG-CSS
   - ♥ Quality assessment tool to be the Society of Thoracic Surgeons (STS), Adult Cardiac Surgery Database (ACSD). The initial report metric would be the composite score "star rating" for coronary artery bypass graft surgery. Other metrics would be selected by the CSS.
   - ♥ All hospitals providing adult cardiac surgery services in Maryland agree to share 6 and 12-month STS reports with MHCC-CAG for review and reporting.
   - ♥ Pursue possibility (with STS/DCRI) regarding mechanism and cost of developing a pooled report of Maryland hospitals as well as ad hoc reports on data elements as needed by the CAG
   - ♥ Semi-annual review of quality metrics the initial elements of which should include STS ACSD Composite Star Ratings with additional elements to be selected by the CAG.
   - ♥ Semi-annual review corresponds to receipt of hospital reports from DCRI. While these reports are 6 months in arrears, the data have been subjected to quality review and audit by both STS and hospitals.
   - ♥ Semi-annual meetings with format and location to be selected by the CAG.
     - ♥ Meetings could be held in a central location. Alternatively, holding the meetings on a rotating basis in each hospital may have value by providing opportunities for more collaborative initiatives, e.g., showcasing specific programs, care patterns, and clinical areas of excellence.

4. Quality improvement initiatives
   - ♥ Examination of One-Star programs for individual program improvement opportunities
   - ♥ Examination of Three Star programs for collaborative program improvement of all hospitals.
   - ♥ Examination of additional clinical areas to improve quality of programs for all Maryland patients as determined by the CAG.

5. Suggested thresholds for focused program review
   - ♥ Two successive 6-month reporting periods with a One Star composite rating
     - ♥ This parameter is being used by the Michigan cardiac surgery collaborative group. Use of two successive 6-month intervals would reduce the impact of adverse event clustering
     - ♥ Annual surgical case volume less than 100 (Note: A "case" would be defined as a procedure record submitted to the STS-ACSD.)

6. Program and data audit
   - ♥ Audit of data, and of process, outcome and other quality measures would require significant resources that should be provided by MHCC.
   - ♥ Options:
     - ♥ CAG-CSS perform vs external agent (STS, IFMC)
     - ♥ "Blinded" vs not blinded
   - ♥ Quality threshold: One Star composite ratings for 4 consecutive 6-month reporting periods (further discussion needed)
   - ♥ Annual surgical case volume threshold: less than 100 for 2 consecutive years (further discussion needed)
   - ♥ Other quality thresholds to be determined by CSS

7. Threshold for approval of new cardiac surgery program
   - ♥ Maintain current level of 200 surgical cases projected annually without adverse impact on other Maryland state programs. (This is the current Maryland State Health Plan rule.)
   - ♥ Require participation in STS-ACSD and reporting to CAG as above. Require review of reports and data from first 6 and 12 months to assist new programs to improve quality of data submission.
   - ♥ Maintain other elements per current regulations.

Summary of Questions ("Q") and Discussion ("D"):

D: Dr. Dehmer commended Dr. Hiratzka on his proposal, and recommended that the proposal could be a model for what the CAG's PCI oversight program could be, moreover, it could be a general model for revascularization.

There was extensive discussion of how or whether the STS registry evaluates the appropriateness of surgery -- While the STS database and analysis address outcomes after a procedure; what about the issue of who gets surgery? (i.e, indications for surgery?) How does one know that a hospital is doing the right surgery on the right patient? It was noted that Maryland is a state where there was a visible problem related to appropriateness of revascularization procedures.

Dr. Hiratzka believes that addressing the appropriateness question will require extensive resources. Dr. Dehmer pointed out that the ACC/AHA appropriate use guideline document is expected to cover both PCI and CS. Dr. Horneffer noted that appropriateness data could be gathered in the cardiac catheterization process.

Dr. Dehmer noted that appropriateness of care in PCI, using NCDR data, is used primarily for evaluation of very complicated patients/procedures. Example: it may be typical to do PCI on patients with single vessel coronary artery lesion, but if the patient has had previous procedures and has re-stenosed, then another PCI is not appropriate. Dr. Massimiano noted that STS data actually include indications for surgery – elective, urgent, emergent; it addresses patient diseases and co-morbidities, so one can tease out a lot of information regarding appropriateness.

Despite agreement that, in the current regulatory climate, hospitals have become somewhat comfortable in sharing data, there was concern expressed about the star rating system. Dr. Hiratzka noted that the star rating format is useful as an opportunity to look at relatively poor performing (One Star) and relatively high-performing (Three Star) programs to see why Three Star sites are doing so well. It was noted that, based on a composite score, mortality comprises 70-80% of the weight of the overall score. Another concern was that use of the star system will tend to turn it into a marketing tool.

In response to concern that hospitals may push some patients out to avoid potentially adverse impact on star rating, Dr. Horvath pointed out that in New York, this had been identified as a problem. However, once New York started doing risk-adjusted measurement, such shifting of patients seemed to have stopped. Dr. Massimiano pointed out that it may sometimes be a good thing for a hospital to send harder patients to another center that can better handle that case and not something that is always undesirable.

Regarding the number of meetings to be held by the CAG-CSS, Dr. Massimiano was asked to describe the Virginia Cardiac Surgery Quality Initiative. Dr. Massimiano noted that in Virginia VCSQI has quarterly meetings. It looks at sets of data, using best practices and benchmarks to get hospitals to perform as well as the best performing hospitals. There may be a movement in Maryland to duplicate VCSQI; Dr. John Conte at Johns Hopkins is working on it.

There was concern expressed regarding the delay between procedure, data entry, and feedback to the site. Per Dr. Hiratzka, the data are sent to Duke, DCRI sends it back and the hospital cleans up the data, then sends it back. This process takes about six months. Dr. Chambers expressed concern that this turnaround is not timely enough for effective quality improvement programs, which must respond with corrective efforts. Dr Williams suggested a 2-tier review program, with all deaths reported within 30 days; for certain rare events; they can have a different level of responsiveness.

With respect to the threshold for focused program review [volume below 100 per year],

Several CAG members argued that this threshold is acceptable for focused review, but not for the "death penalty" (program closure). It was suggested that low-volume programs have more scrutiny of mortality.

Regarding data audit and external review, Dr. Hiratzka asked: How much? How often? Who does it? Who supports it? Blinded vs. non-blinded?

At STS, eight percent of sites will be audited; between 25-30 cases are audited at each site, and the hospital cost for the audit is in the mid five-figure range. Hospitals are chosen at random; cases are randomly selected.

Dr. Horneffer observed that if a subcommittee is non-punitive, then there will be less fear about manipulating data; we could generate a climate of collegiality. Ms. Saunders noted that with so many current reviews of data on a state level, organizations will want the data audited, especially if there is public reporting.

Dr. Dehmer noted that NCDR has an audit program that emulates the STS process. An independent group examines 25 records that are all source documents and does not look at angiograms, they look at the report. A recent *JACC* article by Messenger describes the next phase of NCDR auditing; NCDR has recognized the potential for gaming the program, so NCDR auditing will be ratcheted up. Participating sites are required to undergo the audit if chosen.

Dr. Williams argued that "if we don't look at angiograms, we are not doing a good job."

With respect to the threshold for program closure [One Star composite rating for four consecutive six-month reporting periods],

Dr. Chambers argued that a way to handle true outliers is needed, and the data delay in the STS process is a problem for this type of review. A timeframe of four successive periods of six months will only give problem hospitals one six-month period to correct.

Additional concern was expressed about delays in the STS data review and feedback program, as well as the need for careful review of patient selection and appropriateness of surgical procedures.

Several suggested that the volume threshold be the same for approval of new cardiac surgery programs and for ongoing review of established programs. The straw man proposal has a volume threshold of 100 for established programs, and 200 for new programs.

Before adjourning the meeting, Dr. Hiratzka asked the CAG members to think about and provide further feedback regarding: 1) Thresholds for program review, program closure, and new program approval; 2) how to build an effective audit program; 3) elements and processes for "focused review" ; and 4) final review processes for recommendation to close a program.